UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CAROL ANN BEKEMEYER,

Plaintiff

v.

BRISTOL-MYERS SQUIBB COMPANY,

Defendant.

Civil Action No. '07 CIV 6817

COMPLAINT AND DEMAND FOR JURY TRIAL

COMES NOW Plaintiff, Carol Ann Bekemeyer, ("Plaintiff"), by and through her undersigned counsel, and sets forth her Complaint for damages against the Defendant as follows:

NATURE OF THE ACTION

1. This is an action to recover damages for personal injuries suffered by Carol Ann Bekemeyer as a direct and proximate result of the Defendant's, Bristol-Myers Squibb Company (hereinafter referred to as "BMS") negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, advertising, promoting, marketing, distribution, labeling, and/or sale of the antibiotic Tequin (also known as "Gatifloxacin"). Ms. Bekemeyer brings this claim for negligence, strict liability, breach of implied warranty for fitness, breach of implied warranty for merchantability, fraudulent misrepresentation, negligent misrepresentation, fraudulent concealment, intentional infliction of emotional distress, and violation of Florida Deceptive and Unfair Trade Practices Act.

2. Based upon information and belief Defendant also willfully with knowledge, recklessly without knowledge, or mistakenly misrepresented material facts regarding

the safety and efficacy of Tequin and such misrepresentations were innocently acted on by Plaintiff in taking Tequin.

3. At all times material hereto, Defendant marketed and sold a product, Tequin, that was not reasonably safe when applied to its intended use in the usual and customary manner.

4. At all times material hereto, Defendant's product, Tequin, was defective and/or unreasonably dangerous.

5. At all times material hereto, Defendant designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled, and/or sold Tequin in the State of Florida.

6. At all times material hereto, Defendant failed to remove Tequin from the market and to provide any, or adequate, warnings to doctors and consumers that taking Tequin could cause, and significantly increase the risk of: diabetes, severe hyperglycemia, and severe hypoglycemia.

PARTIES

7. This is an action for damages which exceeds the minimum jurisdictional limits of this Court. Further, at all times relevant, Plaintiff was a resident of Eustis, Florida in Lake County, is over 21 years of age, ingested Tequin, and was injured in the State of Florida as a result of Defendant's actions inside and/or outside the state of Florida and New York.

8. The Defendant, Bristol-Myers Squibb Company, is a Delaware corporation with its principal place of business in New York. At all times material hereto, this Defendant was in the business of manufacturing, promoting, marketing, developing, supplying,

labeling, testing, selling, and/or distributing the antibiotic Gatifloxacin, also known as Tequin, in the State of Florida.

GENERAL ALLEGATIONS

9. Defendant placed a defective and/or unreasonably dangerous product, Tequin, on the market.

10. As a result of taking Tequin, Plaintiff developed severe hypoglycemia and was hospitalized.

11. Defendant directly or indirectly, negligently and/or defectively made, created, manufactured, assembled, designed, tested, labeled, supplied, packaged, distributed, marketed, advertised, warned, and/or sold in the State of Florida, the antibiotic Tequin.

12. Defendant had control of the design, assembly, packaging, marketing, advertising, manufacturing, labeling, testing, promoting, and/or sale of the antibiotic Tequin.

13. At all times material hereto, the Defendant herein either knew or should have known that the drug was related to and associated with severe and life threatening complications and side effects including but not limited to, dysglycemic events, such as hypoglycemia.

14. Although Defendant knew or should have known of the dangerous risks associated with the use of Tequin, Defendant proceeded to or permitted the drug to be advertised, promoted and/or sold without adequate warnings of the seriousness of the side effects and significance of the increased risk of injury.

15. Tequin was approved by the Food and Drug Administration ("FDA") of the United States on December 17, 1999, and was subsequently introduced into the stream of commerce in the United States market.

16. Tequin is an antibiotic in a class of at least seven fluoroquinolones used to treat a variety of infections, including, but not limited to, lung, sinus, skin and/or urinary tract infections and certain sexually transmitted diseases, such as gonorrhea and syphilis.

17. Tequin offers no unique benefit over the other fluoroquinolones; however, it is associated with unique, severe, life-threatening risks that are not associated with many other fluoroquinolones.

18. Defendant represented to the public that Tequin was as safe and effective as other fluoroquinolones. Defendant failed to make sufficient changes in these representations, labeling, or physician communications to distinguish Tequin from other fluoroquinolones and to alert health care providers and patients that Tequin had special or unique risks.

19. In 2001, case reports of Tequin-associated dysglycemia in both diabetics and non-diabetics were being published in medical literature. It was not until October 2002, that BMS changed the Tequin label to include any information about gatifloxacin-associated dysglycemic risks. Even then, the labeling changes were inadequate and downplayed the severity and level of risk of dysglycemia associated with Tequin.

20. In 2003, in the Canadian Adverse Reaction Newsletter, it was reported that after a review of Health Canada's database of spontaneous reports, from February 2001 to February 2003, there was an indication that hyperglycemia and hypoglycemia were reported more frequently with Tequin than with other quinolones. Specifically, there were 28 serious reports of abnormal glucose metabolism associated with Tequin, 19 hospitalizations, and two deaths.

21. In 2003, the drug was contraindicated in Japan for diabetics; however, no such contraindication appeared in the United States label until February of 2006.

22. Despite the data available to the Defendant, it failed to adequately alter the drug inserts and/or labeling and/or promoting to indicate the severe risks, and potentially fatal, dysglycemic reactions. While the aforementioned studies and data (dating back to 2002) indicated a strong correlation between Tequin patients with diabetes and the adverse reaction of severe hypoglycemia, the labeling change by BMS in January 2004 did not adequately address the seriousness of this adverse reaction or the significance of the increased risk.

23. Defendant BMS revised its package insert four times, however, at no time did the insert adequately address and clarify the drug's tendency to cause severe dysglycemic reactions. It merely referred to the reaction as a "disturbance" in blood glucose, effectively deluding doctors and patients into thinking that Tequin was safe. Moreover, BMS's label discounted and diluted (1) existing studies and articles associating Tequin with severe dysglycemia; and (2) its own references to blood glucose disturbances in its label.

24. As Frothingham reported in his Glucose Homeostasis Abnormalities Associated with Use of Gatifloxacin study in November of 2004, an official publication of the Infectious Diseases Society of America, there was a 56-fold increase in severe glucose homeostasis abnormalities and gatifloxacin-associated dysglycemia.

25. On February 15, 2006, Defendant BMS revised the labeling of Tequin contraindicating the drug for use in diabetic patients - unfortunately for Ms. Bekemeyer, it was not until a full year after her ingestion of Tequin. Additionally, the Defendant strengthened the warning in reference to dsyglycemia and included other risk factors. However, as alleged in the Public Citizen petition, filed May 1, 2006, this fourth label change was also an insufficient remedial action for a drug that carries a unique risk without a unique clinical benefit as compared to the other fluoroquinolones.

26. Upon information and belief, on February 15, 2006, despite changing its new labels to include a contraindication for diabetics, the Defendant did not provide a timely warning to those who had recently purchased or been prescribed Tequin.

27. On March 1, 2006, a study by Park-Wyllie, et al, published in the New England Journal of Medicine showed that all patients (diabetic or non-diabetic) having received Tequin had approximately 17 times the odds of having a hyperglycemic episode and 4 times the odds of having a hypoglycemic episode compared with other antibiotics. Again, the data used in this study was available to Defendant as early as April 2002.

28. On May 2, 2006, Defendant BMS quietly announced to its shareholders that it would no longer manufacture Tequin for economic reasons. However, this notice again was grossly inadequate and did nothing to protect the public's health given the data that is known and because there was no intention by the Defendant to stop selling the drug already in the channels of commerce.

29. The representations made by the Defendant were false and misleading and allowed the continuation of treatment of patients with Tequin and subsequent harm to numerous patients. Moreover, by making such representations the Defendant has concealed the facts giving rise to Tequin patients' causes of action, including the facts involved in this Plaintiff's claims.

30. On or about mid to late January, 2005, Plaintiff Carol Ann Bekemeyer was given Tequin by her physician.

31. Plaintiff, Carol Ann Bekemeyer, took Tequin on or about February 1 and 2, 2005, and experienced a severe hypoglycemic reaction. Although Plaintiff had diabetes prior

to taking Tequin, the Plaintiff had not suffered severe hypoglycemia that resulted in hospitalization.

32. As a direct and proximate result of Defendant placing the drug into the stream of commerce, Plaintiff suffered an injury and developed a severe and life threatening disease.

33. Plaintiff has also incurred significant medical, hospital, and/or pharmaceutical expenses, lost wages and/or other economic loss and will continue to incur such expenses and losses as a result of the Defendant's conduct.

34. Upon information and belief the Defendant promoted and marketed Tequin. In conjunction with its promotion and marketing, false, diluted and/or fraudulent information was provided to pharmacists, consumers, and prescribing physicians about the risks and supposed benefits of this drug. Upon information and belief, and in furtherance of its promotion, the Defendant supplied false and misleading marketing and promotional material and programs to unsuspecting pharmacists and prescribing physicians. As a result of the sales of Tequin, Defendant reaped profits and sales of Tequin within Florida.

35. Upon information and belief, the promotional pieces contained false and fraudulent misrepresentations regarding the safety and efficacy of Tequin. Thus, Defendant affirmatively assumed a duty to detect and warn consumers and their doctors, including Plaintiff and her doctor, and Plaintiff reasonably relied upon those representations to her detriment in taking Tequin. Defendant breached that duty when it marketed, promoted, and/or sold drugs to the Plaintiff and her doctor without adequately warning them about the dangers associated with the use of Tequin.

COUNT I
STRICT LIABILITY

36. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 35 above, with the same force and effect as if fully set forth herein.

37. Defendant is strictly liable for violating Florida product liability law as set forth in section 402A of the *Restatement (Second) of Torts* because it defectively designed, and/or defectively manufactured Tequin and/or failed to adequately warn consumers and physicians of the risks associated with Tequin.

38. The drug, Tequin, was defective and/or created an unreasonably dangerous condition when it was produced by and left the possession of the Defendant in that it significantly increased the risk of and caused severe and life threatening complications and side effects, including, but not limited to, dysglycemic events such as hyperglycemia, hypoglycemia, diabetes, diabetic coma, diabetic hyperglycemic coma, diabetic hyperosmolar coma, diabetic ketoacidosis, hypoglycemic coma, and hyperosmolar state.

39. Plaintiff used the drug for its intended purpose, i.e. – to fight an infection/illness and get well/feel better.

40. The facts are such that the Plaintiff could not have discovered the defect in Tequin through the exercise of reasonable care and had no way of realizing its dangerous condition.

41. Unlike the Plaintiff, the Defendant, as manufacturer and distributor of a prescription drug, is held to the level of knowledge of an expert in the field.

42. The prescribing physician did not have substantially the same knowledge of the defect as the Defendants.

43. Defendant failed to provide to the prescribing physician a warning that accurately or adequately communicated the level of increased risk of severe dysglycemia to patients including diabetic patients.

44. The warnings that were given by the Defendant to the prescribing physicians were not accurate, clear, and/or were vague and ambiguous.

45. The Defendant had a continuing duty to warn the Plaintiff and/or the prescribing physicians of the dangers associated with the drug, current research identifying increased risks of injury, and contraindications for diabetic patients.

46. Defendant, BMS, failed to provide a reasonably safe alternative formulation of the drug when Defendant BMS knew or should have known that other antibiotics were available and existing in the market which could fight infection in patients without subjecting them to the risk which Tequin subjected the patient.

47. At all times material to this action, Defendant engaged in the business of designing, distributing, supplying manufacturing, marketing, promoting and/or selling the drug Tequin, which is defective and/or created an unreasonably dangerous condition to consumers, including Plaintiff, when put to its intended use.

48. At all times material to this action, Tequin was designed, sold, distributed, supplied, manufactured, marketed and/or promoted by Defendant was expected to reach, and did reach, consumers in the State of Florida, including Plaintiff, without substantial change in the condition in which it was sold.

49. At all times material to this action, Tequin was designed, sold, marketed, distributed, supplied, manufactured and/or promoted by Defendant in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce.

50. At the time Tequin left the possession of the Defendant, the product was defective and/or created an unreasonably dangerous condition when it was designed, manufactured, marketed and packaged by the Defendant in that, among other ways:

a. It caused injury to the user far beyond any warned, noticed, expected or reasonable side effect or adverse reaction and when placed in the stream of commerce it contained unreasonably dangerous defects subjecting Plaintiff to risks from expected or known usage, including bodily injury, which exceeded the benefits of the drug;

b. When placed in the stream of commerce it was defective in design and formulation making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the taking of equivalent antibiotics;

c. It contained insufficient and/or ineffective warnings to alert consumers and users to the risks of injury and death by dysglycemia including hyperglycemia, hypoglycemia, diabetes, and other serious side effects or reactions;

d. The drug caused harmful side effects which outweighed its potential utility;

e. It was insufficiently tested;

f. There were insufficient instructions on the proper use of the drug;

g. There was misleading advertising and promotion concerning the safety and benefits of using the drug;

h. There were inadequate post-marketing warnings or instructions because, after the Defendant knew or should have know of the significant risks previously described, the Defendant failed to provide adequate warnings to users and consumers, and/or their physicians, and continued to promote the sale and use of the drug;

i. The aforesaid drug had not been materially altered or modified prior to the use of said drug by Plaintiff;

j. The drug was not accompanied by adequate instructions and/or warning to apprize consumers, including Plaintiff, or their doctors, of the full nature or extent of the risks and side effects associated with the use of Tequin, thereby rendering Defendant liable to Plaintiff pursuant to the relevant sections of Section 402A of the *Restatement (Second) of Torts*; and

k. Defendant placed Tequin in the stream of commerce when they knew or should have known that Tequin posed a substantial risk of harm to consumers utilizing Tequin.

51. As a direct and proximate result of the defective and/or unreasonably dangerous condition of the drug, Plaintiff suffered significant physical injuries and endured substantial pain and suffering. She incurred expenses for medical treatment, loss of capacity for the enjoyment of life and other losses and damages recognized by Florida law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from Defendant, as alleged herein.

52. WHEREFORE, Plaintiff demands judgment against Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT II
NEGLIGENCE

53. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 52 above, with the same force and effect as if fully set forth herein.

54. Defendant negligently[1] caused the Plaintiff harm.

55. Defendant directly or indirectly, negligently and/or defectively made, created, manufactured, assembled, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold, in the State of Florida, the drug Tequin.

56. At all times material hereto, Defendant had a duty to Plaintiff to exercise reasonable care in design, manufacture, testing, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, promotion, sale and warning related its respective drug.

57. Defendant breached that duty and was negligent in its actions, misrepresentations, and/or omissions toward Plaintiff in the following ways:

a. Failed to include accurate and adequate warnings with the drug that would alert consumers and physicians to the level of risks and seriousness of side affects of the drug of which it had actual or constructive knowledge;

b. Failed to adequately and properly test the drug before placing the drug on the market;

c. Failed to conduct sufficient testing on the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, severe dysglycemia;

[1] *Bearint v. Johnson Controls, Inc., et al*, 2006 U.S. Dist. LEXIS 46571, *5-6 (M.D.F.L. 2006).

d. Failed to adequately warn Plaintiff and the prescribing physicians that use of the drug carried risk of severe and life threatening disability due to dysglycemia;

e. Failed to warn Plaintiff and the prescribing physician that use of the drug carried a risk that hospitalization may become necessary to correct the severe blood glucose disturbances;

f. Failed to provide adequate post-marketing warning or instructions after the Defendant knew or should have known of the significant risks of severe and life-threatening dysglycemia from the use of the drug;

g. Failed to adequately warn the Plaintiff and the prescribing physician that the drug could cause hypoglycemia, hyperglycemia and diabetes;

h. Failed to adequately warn the Plaintiff and prescribing doctors that the drug product could create a significantly increased risk of disturbed glucose homeostasis in patients without diabetes;

i. Encouraged use while underplaying the side effects to doctors and the public in order to make a profit from sales.

58. Defendant knew or should have known that the drug caused unreasonably dangerous risks and serious side effects of which the Plaintiff and the prescribing physician would not be aware. Defendant nevertheless advertised, marketed, sold and/or distributed the drug knowing that there were safer alternatives and products to treat the same infection.

59. As a direct and proximate result of the negligence of Defendant, Plaintiff suffered significant physical injuries and endured substantial pain and suffering. She incurred expenses for medical treatment, loss of capacity for the enjoyment of life and other losses and

damages recognized by Florida law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from Defendants, as alleged herein.

60. WHEREFORE, Plaintiff demands judgment against Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT III
BREACH OF IMPLIED WARRANTY OF FITNESS

61. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 60 above, with the same force and effect as if fully set forth herein.

62. The Defendant violated the implied warranty of fitness for particular purpose under Fla. Stat. § 672.314 of the Florida Uniform Commercial Code.

63. Defendant had reason to know that the Plaintiff and her doctor needed to use its product for the safe and efficient treatment of illness. Moreover, Defendant had reason to know that both the Plaintiff and her doctor were relying on the Defendant's skill and judgment to select and furnish suitable goods.

64. When Defendant placed the drug into the stream of commerce, they knew of the use for which the drug was intended and impliedly warranted the product to be safe and fit for such use.

65. Plaintiff and her doctor reasonably relied upon the expertise, skill, judgment and knowledge of Defendant and upon the implied warranty that the drug was fit for use for the safe treatment of respiratory illnesses.

66. The drug was not safe or fit for its intended use because the product was and is unreasonably dangerous and unfit for the ordinary purposes for which it is used.

67. As a direct and legal result of the breach of warranty of fitness by Defendant, Plaintiff suffered significant injuries and endured substantial pain and suffering and emotional distress. Plaintiff incurred, and will continue to incur, expenses for medical treatment, loss of capacity for the enjoyment of life, and other losses and damages recognized by Florida law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from Defendant, as alleged herein.

68. WHEREFORE, Plaintiff demands judgment against Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT IV
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

69. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 68 above, with the same force and effect as if fully set forth herein.

70. In violation of Fla. Stat. § 672.314 of the Florida Uniform Commercial Code, the Defendant breached the implied warranty of merchantability.

71. Defendant is a merchant with respect to the sale of pharmaceuticals.

72. Defendant's goods, Tequin, did not pass without objection in the trade under its contract description.

73. Tequin is a fungible good that could be interchanged with several other fluoroquinolone antibiotics and which was not of average quality within its contract description because it was unreasonably dangerous.

74. Because of its unreasonable dangerousness, Tequin is not fit for the ordinary purposes for which such goods are used.

75. Tequin did not run within the variations of quality and safety permitted.

76. Tequin was not adequately labeled and did not warn doctors or their patients that taking Tequin would significantly increase the patient's risk of developing diabetes or a severe blood sugar disorder.

77. When Defendant placed the drug into the stream of commerce, they knew of the use for which the drug was intended and impliedly warranted the products to be merchantable quality and safe fit for such use.

78. Plaintiff reasonably relied upon the expertise, skill, judgment and knowledge of Defendant and upon the implied warranty that the drug was of merchantable quality and fit for use for the treatment of respiratory illnesses in patients.

79. Tequin was not of merchantable quality because it was and is unreasonably dangerous and unfit for the ordinary purposes for which it was and is used.

80. As a direct and legal result of the breach of warranty of Defendant, Plaintiff suffered physical injuries and endured substantial pain and suffering. She incurred, and will continue to incur, expenses for medical treatment, loss of capacity for the enjoyment of life and other losses and damages recognized by Florida law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from Defendant, as alleged herein.

81. WHEREFORE, Plaintiff demands judgment against Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT V
NEGLIGENT MISREPRESENTATION

82. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 81 above, with the same force and effect as if fully set forth herein.

83. The Defendant made statements regarding Tequin's safety and efficacy that were false.

84. Defendant was negligent in making statements regarding Tequin's safety and efficacy because it should have known the statements were false.

85. The Defendant intended that Plaintiff and her doctors would rely on its false statements.

86. Plaintiff and her doctors justifiably acted on Defendant's misrepresentations and Plaintiff was injured as a direct result of such reliance.

87. Defendant negligently misrepresented to the Plaintiff, her physician, and the general public the safety and effectiveness of the drug and negligently concealed material, adverse information regarding the safety and effectiveness of the drug.

88. Defendant's misrepresentations were communicated to the prescribing physician and/or consumers with the intent that they reach the Plaintiff.

89. Defendant either knew or should have known that the representations were false.

90. Defendant made the misrepresentations and/or actively suppressed this information with the intention and specific desire that the Plaintiff, the prescribing physician or other dispensing entities and the consuming public would rely on such in selecting the drug as treatment for infections and illness.

91. Defendant negligently diluted and/or suppressed material, adverse information regarding the safety and effectiveness of their product.

92. Defendant misrepresented adverse information at a time when the Defendant knew, or should have known, that their drug product had defects, dangers, and/or

characteristics that were other than what the Defendant had represented to the prescribing doctors or other dispensing entities, the FDA, and the consuming public, including the Plaintiff herein. Specifically, the Defendant misrepresented to Plaintiff, her prescribing physicians or other dispensing entities, the FDA and the consuming public:

a. That the drug was as safe as other quinolones in its class;

b. That it was safe to prescribe the drug to patients with diabetes;

c. That despite knowing that there had been insufficient or inadequate testing of the drug; the drug was marketed, promoted and/or sold as if it were full and adequately tested;

d. That there had been sufficient studies regarding the safety and efficacy of the drug for use in both diabetics and non-diabetics;

e. That although prior studies, research, reports and/or testing had been conducted linking the use of the drug, to serious adverse reactions including, but not limited to severe and life-threatening dysglycemia, hypoglycemia and/or hyperglycemia, that the drug was safe and effective for the treatment of infection;

f. That it knew, or should have known of adverse event reports, animal studies, case reports and other studies associating events of hypoglycemia, hyperglycemia, dysglycemia and death to the drug;

g. The nature and extent of beneficial health effect the drugs would provide the user.

h. That the drug was safe and efficient even though in reality it significantly increased the risk of diabetes and hypoglycemic and hyperglycemic episodes.

93. Defendant negligently diluted its warnings and advertisements as to the dangerousness Tequin posed by (1) presenting confusing and contradictory information in its material; and (2) misrepresenting material facts.

94. The misrepresentations were perpetuated directly and/or indirectly by the Defendant, its sales representatives, employees, distributors, agents and/or detail persons.

95. The misrepresentations by the Defendant constitute a continuing tort.

96. Through Defendant's manufacturer product insert(s), the Defendant manufacturer continued to misrepresent the potential risks and complications associated with Tequin.

97. Defendant has a post-sale duty to warn Plaintiff about the potential risks and complications associated with Tequin in a timely manner.

98. Defendant misrepresented the safety and efficacy of the drug product in their labeling, advertising, product inserts, promotional materials, or other marketing efforts.

99. Plaintiff and/or the prescribing physician justifiably relied on and/or were induced by the misrepresentations of Defendant to the Plaintiff's detriment.

100. As a direct and legal result of the negligent misrepresentations of the Defendant, Plaintiff suffered physical injuries and endured substantial pain and suffering. She incurred expenses for medical treatment, loss of capacity for the enjoyment of life and other losses and damages recognized by Florida law. Plaintiff has been physically, emotionally, and

economically injured and seeks all damages recoverable by law from Defendant, as alleged herein.

101. WHEREFORE, Plaintiff demands judgment against Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT VI
FRAUDULENT MISREPRESENTATION

102. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 101 above, with the same force and effect as if fully set forth herein.

103. The Defendant intentionally or without knowledge misrepresented material facts regarding Tequin's safety and efficacy that it knew were false.

104. The Defendant intended that Plaintiff and her doctors would rely on its false statements.

105. Plaintiff and her doctors justifiably acted on Defendant's misrepresentations and Plaintiff was injured as a direct result of such reliance.

106. Defendant fraudulently, intentionally and/or negligently misrepresented to the Plaintiff, her physician, and the general public the safety and effectiveness of the drug and/or fraudulently, intentionally and/or negligently concealed material, adverse information regarding the safety and effectiveness of the drug.

107. Defendant's misrepresentations were communicated to the prescribing physician and/or consumers with the intent that they reach the Plaintiff.

108. Defendant either knew or should have known that the representations were false.

109. Defendant made the misrepresentations and/or actively suppressed this information with the intention and specific desire that the Plaintiff, the prescribing physician or

other dispensing entities and the consuming public would rely on such in selecting the drug as treatment for infections and illness.

110. Defendant intentionally diluted and/or suppressed material, adverse information regarding the safety and effectiveness of their product.

111. Defendant misrepresented adverse information at a time when the Defendant knew, or should have known, that their drug product had defects, dangers, and/or characteristics that were other than what the Defendant had represented to the prescribing doctors or other dispensing entities, the FDA, and the consuming public, including the Plaintiff herein. Specifically, the Defendant misrepresented to Plaintiff, her prescribing physicians or other dispensing entities, the FDA and the consuming public:

a. That the drug was as safe as other quinolones in its class;

b. That it was safe to prescribe the drug to patients with diabetes;

c. That despite knowing that there had been insufficient or inadequate testing of the drug; the drug was marketed, promoted and/or sold as if it were full and adequately tested;

d. That there had been sufficient studies regarding the safety and efficacy of the drug for use in both diabetics and non-diabetics;

e. That although prior studies, research, reports and/or testing had been conducted linking the use of the drug, to serious adverse reactions including, but not limited to severe and life-threatening dysglycemia, hypoglycemia and/or hyperglycemia, that the drug was safe and effective for the treatment of infection;

f. That it knew, or should have known of adverse event reports, animal studies, case reports and other studies associating events of hypoglycemia, hyperglycemia, dysglycemia and death to the drug;

g. The nature and extent of beneficial health effect the drugs would provide the user.

h. That the drug was safe and efficient even though in reality it significantly increased the risk of diabetes and hypoglycemic and hyperglycemic episodes.

112. Defendant willfully diluted its warnings and advertisements as to the dangerousness Tequin posed by (1) presenting confusing and contradictory information in its material; and (2) misrepresenting material facts.

113. The misrepresentations were perpetuated directly and/or indirectly by the Defendant, its sales representatives, employees, distributors, agents and/or detail persons.

114. The misrepresentations by the Defendant constitute a continuing tort.

115. Through Defendant's manufacturer product insert(s), the Defendant manufacturer continued to misrepresent the potential risks and complications associated with Tequin.

116. Defendant has a post-sale duty to warn Plaintiff about the potential risks and complications associated with Tequin in a timely manner.

117. Defendant misrepresented the safety and efficacy of the drug product in their labeling, advertising, product inserts, promotional materials, or other marketing efforts.

118. Plaintiff and/or the prescribing physician justifiably relied on and/or were induced by the misrepresentations of Defendant to the Plaintiff's detriment.

119. As a direct and legal result of the intentional misrepresentations of the Defendant, Plaintiff suffered physical injuries and endured substantial pain and suffering. She incurred expenses for medical treatment, loss of capacity for the enjoyment of life and other losses and damages recognized by Florida law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from Defendant, as alleged herein.

120. WHEREFORE, Plaintiff demands judgment against Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT VII
FRAUDULENT CONCEALMENT

121. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 120 above, with the same force and effect as if fully set forth herein.

122. Defendant suppressed and misrepresented material facts regarding Tequin's safety and efficacy that Defendant had an obligation to communicate to Plaintiff and her doctor.

123. Defendant actively concealed information at a time when the Defendant knew, or should have known, that their drug product had defects, dangers, and/or characteristics that were other than what the Defendant had represented to the prescribing doctors or other dispensing entities, the FDA and the consuming public, including the Plaintiff herein. Specifically, the Defendant actively concealed and misrepresented the following material facts to the Plaintiff, her prescribing physicians or other dispensing entities, the FDA and the consuming public:

a. *The drug significantly increased the risk of, and could cause, diabetes.*

b. The drug *should have been contraindicated for patients with diabetes;*

c. The drug carried risks of serious adverse effects;

d. There had been insufficient studies regarding the safety and efficacy of the drug for use in both diabetics and non-diabetics;

e. Prior studies, research, reports and/or testing had been conducted linking the use of the drug, to serious adverse reactions, including, but not limited to severe and life-threatening dysglycemia;

f. Defendant knew, or should have known of adverse event reports, animal studies, case reports and other studies associating events of dysglycemia and death related to the drug; and

g. The number of deaths and severe blood reactions associated with Tequin.

124. The Defendant intended to induce the Plaintiff, her physician and the FDA to act on its suppression and misrepresentation of material facts.

125. The active concealment by Defendant was perpetuated directly and/or indirectly by the Defendant, its sales representatives, employees, distributors, agents and/or detail persons.

126. The active concealment by the Defendant constitutes a continuing tort.

127. Through Defendant's manufacturer product insert(s), the Defendant manufacturer's continued to misrepresent and suppress the potential risks and complications associated with Tequin.

128. Defendant has a post-sale duty to warn Plaintiff about the potential risks and complications associated with Tequin in a timely manner.

129. Defendant suppressed material facts as to the safety and efficacy of the drug product in their labeling, advertising, product inserts, promotional materials, or other marketing efforts.

130. To her detriment, Plaintiff and/or her prescribing physician justifiably relied on and were induced by the Defendant suppression of material facts.

131. As a direct and legal result of the Defendant's suppression and misrepresentation of material facts, Plaintiff suffered physical injuries and endured substantial pain and suffering. She incurred expenses for medical treatment, loss of capacity for the enjoyment of life and other losses and damages recognized by Florida law. Plaintiff has been physically, emotionally, and economically injured and seeks all damages recoverable by law from Defendant, as alleged herein.

132. WHEREFORE, Plaintiff demands judgment against the Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT VIII
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

133. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 132 above, with the same force and effect as if fully set forth herein.

134. Defendant acted intentionally or recklessly, that is, the Defendant intended its behavior when it knew or should have known that emotional distress would likely result, when it:

a. Designed, manufactured, tested, and/or supplied, and/or sold and distributed a defective product to Plaintiff;

b. Concealed and/or diluted the defects in Tequin from Plaintiff and her doctors; and

c. Misrepresented the quality, safety, and usefulness of the drug.

135. Defendant's reckless and outrageous conduct directly impacted and directly involved Plaintiff in that she and/or her physicians decided to purchase, ingest, and/or use the defective and dangerous antibiotic, which Defendant manufactured, sold, and distributed, causing in Plaintiff to suffer and continue to suffer severe emotional distress.

136. Defendant's conduct, above, was outrageous and is intolerable in civilized society.

137. As a direct result of Defendant's misconduct alleged herein, Plaintiff has developed diabetes, suffered a severe hypoglycemic reaction, suffered severe mental pain and anguish, expense and economic loss as previously described rendering Defendant liable for all damages allowed by Florida law.

138. As a direct and legal result of the Defendant's intentional, outrageous conduct, Plaintiff suffered not only physical injuries and pain and suffering, but she also suffered severe emotional distress as well. Such distress is recognized as damages under Florida law. Plaintiff seeks recovery from Defendant for her emotional distress, as alleged herein.

139. WHEREFORE, Plaintiff demands judgment against Defendant for damages, as well as all costs of this action and a trial by jury of all issues to be tried.

COUNT NINE
VIOLATION OF FLORIDA DECEPTIVE AND UNFAIR TRADE PARACTICES ACT[2]

140. Plaintiff repeats, reiterates and realleges the allegations set forth in paragraphs 1 through 139 above, with the same force and effect as if fully set forth herein.

141. Defendant engaged in unfair and/or deceptive practices when it:

[2] Fla. Stat. § 501.204 – 501.211.

a. Designed, manufactured, tested, and/or supplied, and/or sold and distributed a defective product to Plaintiff;

b. Concealed and/or diluted the defects in Tequin from Plaintiff and her doctors; and

c. Misrepresented the quality, safety, and usefulness of the drug.

142. Defendant's unfair and/or deceptive practices were likely to deceive consumers acting in similar circumstances as the Plaintiff.

143. Plaintiff was deceived and harmed as a proximate result of the Defendant's unfair and/or deceptive practices.

PLAINTIFF'S DAMAGES

144. As a result of the combined and concurring violation of Florida product liability law, negligence, breach of implied warranties, fraud, fraudulent concealment, misrepresentations, intentional infliction of emotional distress, violation of Florida Deceptive and Unfair Trade Practices Act, and the design, sale, distribution and promotion of the defective product, Tequin, the above-named Defendant have caused or contributed to cause the following injuries to the Plaintiff:

a. Plaintiff has been caused to suffer, and will continue to suffer, physical injury, pain and suffering, and mental anguish;

b. Plaintiff has been caused to incur, and will continue to incur, medical expenses;

c. Plaintiff has incurred other consequential economic losses, including loss of income and the costs associated with this lawsuit.

145. WHEREFORE, Plaintiff demands judgment against the Defendant, of all kinds and nature as are allowed by law, for all of the counts and causes alleged above, for compensatory and punitive damages, in such an amount as may be awarded to the Plaintiff by a jury.

JURY TRIAL DEMAND

Plaintiff hereby demands a jury trial in this matter.

CAROL ANN BEKEMEYER,
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